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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------|------------------|
| 09/502,984 | 02/11/2000 | Peizhi Luo | A-68126-1/RFT/RMS/SJR | 5952 |
| 7590 02/25/2004 | | | | |
| Flehr Hohbach Test Albright & Herbert LLP four Embarcadero Center Suite 3400 San Francisco, CA 94111-4187 | | | EXAMINER ZARA, JANE J | |
| | | | ART UNIT 1635 | PAPER NUMBER |

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/502,984

Applicant(s)

LUO ET AL.

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-38 is/are pending in the application.
- 4a) Of the above claim(s) 21-30,32,33,37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☒ Claim(s) 31, 34-36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

The request filed on 3-18-02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/502,984 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 20-38 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of the **invention** comprising SEQ ID NO: 37, claims 20, 31, 34-36 in the Paper filed 11-24-03 is acknowledged. The traversal is on the ground(s) that searching all of sequences or mutations claimed would not pose a serious burden on the examiner. Applicants also assert that since the various products claimed spring from a single, computational processing technique, they share common structural and functional properties and thus constitute a single invention. This is not found persuasive because the various products vary in their amino acid sequences and are chemically and biologically distinct, and therefore are different and distinct inventions, not species. Furthermore, the searching of one amino acid sequence or mutation within a polypeptide sequence (e.g. A15S) does not lead to the identification of a different amino acid sequence or product (e.g. a mutation at one or more amino acids of a polypeptide sequence, including or not including the former mutation). The search for each of these mutations, or a combination of any number of these mutations,

does pose a serious burden on both the examiner and the PTO facilities, especially with the existing expansive data bases that one must search in order to perform a proper examination of each claimed invention (i.e. polypeptide sequence).

The requirement is still deemed proper and is therefore made FINAL.

Claims 21—30, 32, 33, 37 and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11-24-03. The elected claims 20, 31, 34-36 have been examined as they pertain to SEQ ID NO: 37, as set forth below.

Claim 20 link(s) the various independent inventions, each comprising different and distinct amino acid sequences. The restriction requirement distinguishing the linked inventions is subject to the nonallowance of the linking claim(s), claim 20. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to erythropoietin receptor analogs comprising numerous mutations throughout various regions of the EPOR, and further comprising a linker and a dimerization motif. The specification and claims do not indicate the distinguishing attributes concisely shared by the members of the genera comprising erythropoietin receptor analogs, linkers or dimerization motifs. The specification does not place any limit on the number of amino acid substitutions in the broad genus comprising erythropoietin receptor analogs, nor does it adequately define the structural specificity of dimerization motifs. The specification furthermore does not place any structural limits on, or adequately define, linkers. Thus, the scope of the claim includes numerous structural variants, and each genus is highly variant because a significant number of structural differences between genus members is permitted. Concise structural features that could distinguish compounds from others in the broad genera comprising

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erythropoietin receptor analogs, linkers and dimerization motifs are missing. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the various genera claimed. Thus, applicant was not in possession of the claimed genera.

Allowable Subject Matter

The sequence of SEQ ID NO: 37 appears free of the prior art of record..

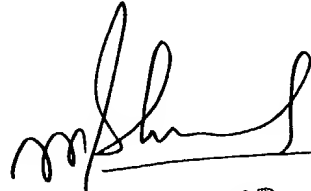
Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

JZ

2-19-04